REMARKS

By this Amendment, Applicants have canceled claims 11-21 and amended claim 1. Claims 1-10 and 24 remain pending in the application. Claim 1 is independent.

The Examiner stated that claims 11-21 were drawn to a non-elected invention and that a complete reply to the present Action must include cancellation of the non-elected claims or other appropriate action. Accordingly, Applicants have canceled claims 11-21.

The Examiner rejected claims 1-4 and 24 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,510,065 to McFarlane taken together with Menges et al., How to Make Injection Molds, 3rd Edition, Hanser Publishers, 2001, pp.401-420 ("Menges"). Also under 35 U.S.C. 103(a), the Examiner rejected claims 1, 2, 6-8 and 10 as being unpatentable over WO 90/00960 to Glocker et al. ("Glocker"), and rejected claims 1, 2, 7 and 8 as being anticipated by U.S. Patent No. 5,032,343 to Jeffs or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Jeffs. In addition, the Examiner also rejected claims 5-10 under 35 U.S.C. 103(a) as being unpatentable over any one of McFarlane, Glocker or Jeffs taken together with Menges and further in view of U.S. Patent No. 6,630,086 to Goral et al.

As set forth in amended claim 1, the present invention is directed to a method for one-piece injection moulding of a soft needle catheter having a hub and a tube-shaped flexible part, both of which parts are formed through the one-piece injection moulding method. The method includes the steps of feeding a molten polymer into a mould having a core which is used to form an interior of the catheter. The mould and the core together define a hub cavity and a tube-shaped cavity for forming the hub and the tube-shaped flexible part, respectively.

The step of feeding includes using a core having a cone-shaped part that extends from the hub cavity into the tube-shaped cavity and a cylindrical part that extends from the distal end (distal relative to the hub) of the cone-shaped part. This core is used to create, *within the tube-shaped cavity*, a tube-shaped flexible part having a cylindrical portion and a cone-shaped portion extending between the hub cavity and the cylindrical portion. The cone-shaped portion facilitates removal of the core when the polymer has been sufficiently cured for the core to be removed. The resulting soft needle catheter formed from the above-described one-step injection moulding method is then removed from the mould when the polymer has been sufficiently cured to be removed. This method of using *a cone-shaped part in the tube-shaped*

cavity to ease release of the core during catheter production, in combination with the cylindrical part at the distal end of the tube-shaped cavity that creates an area having the frictional resistance which is desired during insertion (see page 5, lines 9-11), is not shown or suggested by the prior art.

As discussed more fully in the previous Amendment filed on November 27, 2006, McFarlane discloses a method of in-line injection moulding using a mould cavity portion 20 having a cylindrical cavity 24 around the core pin 22 and a widened upper area around the core pin head 23 representing the hub cavity. The cylindrical cavity 24 has a constant inner diameter in the portion extending from the hub so that McFarlane does not disclose a cone-shaped part between the cylindrical cavity 24 and the hub 23.

Glocker discloses a method for one-piece injection moulding of a soft needle catheter using a mould and a core which together define a cavity composed of a hub cavity 12, 13 and a tube-shaped cavity 11 (see Figure 2 of Glocker). The hub cavity 12, 13 has a cone-shaped part as shown in Figure 2, but this cone-shaped part *does not extend into the tube-shaped cavity* 11. Therefore, Glocker does not disclose using a core having a cone-shaped part that extends from the hub cavity *into* the tube-

shaped cavity to create a cone-shaped part *within the tube-shaped cavity*, as claimed by the present invention.

As just summarized and acknowledged by the Examiner, neither McFarlane nor Glocker disclose or suggest a tube-shaped flexible part having a cone-shaped portion that extends from a hub cavity and a cylindrical portion at the distal end of the cone-shaped portion. Hence, the Examiner has relied upon Menges as teaching this manner of injection molding a catheter.

Menges teaches that the release forces associated with removing the molded catheter from the mold can be reduced by providing a core with slightly tapered walls. However, a person of ordinary skill in the art, upon reading Menges, would conclude that the core should be tapered along its full length with the "greatest permissible taper" in order to gain maximum reduction of the release forces. This is contrary to the presently claimed invention.

As claimed herein, the core includes a slightly tapered part extending from the hub part and into the tube-shaped part but, where the core forms the end opposite of the hub, the core is cylindrical. As noted in the specification, the cone-shaped part of the core eases the release of the core during the molding process. The cylindrical part, however, creates an area with the frictional

resistance which is desired during the insertion (see page 5, lines 9-11). Hence, contrary to the teaching of Menges, the tube-shaped flexible part produced according to the claimed method includes both a cylindrical part having an inner cylindrical profile and a cone shaped part having an inner cone shaped profile. There is nothing in Menges to suggest this combination.

For at least the foregoing reasons, claim 1 is patentable over each of McFarlane and Glocker in view of Menges.

Jeffs is directed to a method of producing medical micro pipette tips. As the cone-shaped part 24 of the pipette 20, 60 remote from the tip cannot be flexible (see column 4, lines 18-27 and lines 55-57), the structure disclosed by Jeffs is not analogous to the claimed invention no matter how Jeffs is interpreted.

First, if the cone-shaped part 24 of the micro pipette 60 is to be equated with the hub 3 of the presently claimed invention, then the tube-shaped flexible part 64 of the micro pipette tip does not have a cone-shaped part, but is entirely cylindrical.

Alternatively, if only the upper part of the cone-shaped part 24 of the micro pipette 60, i.e., that part stretching from the upper end adjacent reference numeral 30 down to the shoulder 34 (see Figure 6 of Jeffs), is to be compared with the hub 3 of the presently claimed invention, then the tube-shaped part which

stretches from the shoulder 34 to the end 66 and is disclosed as providing substantial rigidity, cannot be described as a "flexible part".

With respect to the lack of flexibility in portion 24 of Jeffs, the Examiner stated that the present claims do not require that the entire tube-shaped part be flexible. In requesting reconsideration of this statement, Applicants point out that the component at issue is claimed as a "tube-shaped flexible part" and not a "flexible tube-shaped part". In the latter case, the language would define a tube-shaped part that may have limited flexibility which could be interpreted as the Examiner has stated. But in the claimed language, the primary modifier defining the "part" is that it is "flexible"; it is a "flexible part" that also happens to be tube-shaped. This is not true of portion 24 of Jeffs. Accordingly, claim 1 is patentable over Jeffs and reconsideration and withdrawal of the rejection on the basis of Jeffs is requested.

Claim 1 being in condition for allowance, claims 2-10 and 24 are also allowable as claims properly dependent on an allowable base claim and for the subject matter contained therein.

The foregoing amendments are not considered to raise new issues not already presented and therefore are proper after final

action. Entry thereof and allowance of the application is requested.

Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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